

Bausch & Lomb Soothe® Xtra Hydration Lubricant Eye Drops

MATERIAL SAFETY DATA SHEET

Effective Date: 3/9/10 Supersedes: None

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Section 1: CHEMICAL PRODUCT AND COMPANY IDENTIFICATION

PRODUCT:

Product Name: Bausch & Lomb Soothe® Xtra Hydration Lubricant Eye Drops
Product Description: Sterile aqueous solution for the eyes
Product Code(s): 622233, 622234
Intended Use: Dry eye moisturizing drops

COMPANY IDENTIFICATION:

Bausch & Lomb, Incorporated
1400 N. Goodman Street
Rochester, New York 14609

For Information: 1-800-553-5340

EMERGENCY TELEPHONE NUMBER:

24-Hour Emergency (Infotrac): 1-800-535-5053

International (Infotrac): 1-352-323-3500

Section 2: HAZARD(S) IDENTIFICATION

CLASSIFICATION: Not classified*

LABELING:

Pictograms: Not required

Signal Word: Not required

Hazard Statements: Not required

Precautionary Statements:

This product is intended as an eye drop.
Do not use if allergic to any ingredient.
Store at room temperature 59-77°F (15-25°C).
Use only in accordance with label instructions.
Keep Out of Reach of Children.

* Based on ingredients

POTENTIAL HEALTH EFFECTS

EYE:

Non-irritating to the eyes when used as directed.

SKIN:

Non-irritating to skin or mucous membranes when used as directed.

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Section 2: HAZARD(S) IDENTIFICATION (cont.)

INGESTION:

Small amounts (a tablespoonful) swallowed are not likely to cause injury; swallowing amounts larger than that may cause gastrointestinal irritation.

INHALATION:

No hazard when used as directed.

CHRONIC HEALTH EFFECTS

No known chronic hazards.

CARCINOGENICITY:

NTP: CAS# 25013-16-5, Classified 2 (some evidence)*

IARC: CAS# 25013-16-5, Classified 2B (possibly carcinogenic to humans)*

OSHA: No ingredients listed.

* Based on the observation of increased incidence of stomach carcinomas in rats after oral ingestion 104 weeks (NOEL = 10,000 ppm). In another study, this amount roughly corresponded to approximately 450 mg/kg/day.

Section 3: COMPOSITION / INFORMATION ON INGREDIENTS

CAS #	Chemical Identitiy	Concentration, % W/W	EINECS / ELINCS #
1303-96-4	Sodium Borate	< 0.1	NA
10043-35-3	Boric Acid	< 1.0	233-139-2
56-81-5	Glycerin	< 1.0	200-289-5
57-55-6	Propylene Glycol	< 1.0	200-338-0
9005-38-3	Sodium Alginate	< 1.0	NA
124-43-6	Carbamide Peroxide	< 1.0	204-701-4
3794-83-0	Hydroxyalkyl Phosphonate (30%)	< 0.1	223-267-7
25013-16-5	Butylated Hydroxyanisole (BHA)	< 0.01	246-563-8
7732-18-5	Purified Water	> 95	231-791-2

Section 4: FIRST AID MEASURES

EYES:

If discomfort or irritation develops, immediately discontinue product use and contact your eye care professional.

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Section 4: FIRST AID MEASURES (cont.)

SKIN:

No specific treatment is necessary since this material is not likely to be hazardous by contact with the skin or mucous membranes.

INGESTION:

No specific treatment is necessary since this material is not likely to be hazardous by ingestion. If large quantities are accidentally ingested (greater than a tablespoon), get medical attention immediately.

INHALATION:

No specific treatment is necessary since this material is not likely to be hazardous by inhalation. If exposed to excessive levels of mists, remove to fresh air and get medical attention if cough or other symptoms develop.

Section 5: FIRE FIGHTING MEASURES

FLAMMABLE PROPERTIES:

Flash Point: Non-Combustible

Method: NA

EXTINGUISHING MEDIA:

Water spray, carbon dioxide, dry chemical powder or appropriate foam for surrounding fire.

HAZARDOUS COMBUSTION PRODUCTS:

None identified.

SPECIAL FIRE FIGHTING INSTRUCTIONS:

As in any fire, wear self-contained breathing apparatus and full protective gear.

Section 6: ACCIDENTAL RELEASE MEASURES

General Information:

Contain spill and absorb with a suitable inert material, then place in a chemical waste container. Dispose of in accordance with Section 13.

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Section 7: HANDLING AND STORAGE

HANDLING:

No special handling is required. Use in accordance with product literature.

STORAGE:

Store at room temperature 59-77°F (15-25°C) to maintain product integrity.

Section 8: EXPOSURE CONTROLS / PERSONAL PROTECTION

CONTROL PARAMETERS:

OCCUPATIONAL EXPOSURE LIMITS / GUIDELINES

CAS #	COMPONENT NAME	OCCUPATIONAL EXPOSURE LIMITS / GUIDELINES										UNITS
		OSHA PEL		ACGIH TLV		NIOSH REL		IRELAND		HSE		
		TWA	STEL	TWA	STEL	TWA	STEL	TWA	STEL	TWA	STEL	
1303-96-4	Sodium Borate	NE	NE	2	6	5	NE	5	NE	5	NE	MG/M3
10043-35-3	Boric Acid	NE	NE	2	6	NE	NE	NE	NE	NE	NE	MG/M3
56-81-5	Glycerin	15*5**	NE	10	NE	NE	NE	10	NE	10	NE	MG/M3
57-55-6	Propylene Glycol	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NA
9005-38-3	Sodium Alginate	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NA
124-43-6	Carbamide Peroxide	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NA
3794-83-0	Hydroxyalkyl Phosphonate (30%)	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NA
25013-16-5	Butylated Hydroxyanisole (BHA)	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NA
7732-18-5	Purified Water	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NA

N/E: Not Established OSHA: Occupational Safety & Health Administration

N/A: Not Applicable PPM: Parts per Million

ACGIH: American Conference of Governmental Industrial Hygienists

NIOSH: National Institute for Occupational Safety & Health

* Total Mist

** Respirable Mist

TWA: 8-Hour Time-Weighted Average

STEL: Short-Term Exposure Limit

C: Ceiling Limit

REL: Recommended Exposure Limit

NOTE: Limits/standards shown for guidance only. Follow applicable regulations.

ENGINEERING CONTROLS:

Use with good general ventilation. No special controls required.

RESPIRATORY PROTECTION:

No special controls or personal protection required under conditions of intended use.

SKIN PROTECTION:

No special controls or personal protection required under conditions of intended use.

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Section 8: EXPOSURE CONTROLS / PERSONAL PROTECTION (cont.)

EYE PROTECTION:

No special controls or personal protection required under conditions of intended use.

ADDITIONAL PROTECTIVE CLOTHING & EQUIPMENT:

NA

Section 9: PHYSICAL AND CHEMICAL PROPERTIES

Physical State:	Liquid
Color:	Clear to light yellow liquid
Odor:	Odorless
Odor Threshold:	Not determined
pH-Value:	6.6 – 7.1
Melting Point:	Not applicable
Freezing Point:	Not determined
Initial Boiling Point:	Not determined
Flash Point:	Not applicable
Evaporation Rate:	Not determined
Flammability (solid,gas):	Not flammable
Explosion Limits:	Not determined
Vapor Pressure:	Not determined
Vapor Density:	Not determined
Specific Gravity (H₂O=1):	1.01
Solubility:	Highly soluble in water
Partition Coefficient:	Not determined
Auto-Ignition Temperature:	Not applicable
Decomposition Temperature:	Not determined
Viscosity:	Not determined
Osmolality:	225-260 mOsm/kg

Section 10: STABILITY AND REACTIVITY

GENERAL:

Stable under normal conditions.

INCOMPATIBLE MATERIALS AND CONDITIONS TO AVOID:

None.

HAZARDOUS POLYMERIZATION:

Will not occur.

HAZARDOUS DECOMPOSITION:

None identified.

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Section 11: TOXICOLOGICAL INFORMATION

RTECS No.: SC7310000

Sodium Borate

Toxicity Data: ORL-MOUSE LD50: 3250 MG/KG

RTECS No.: ED4550000

Boric Acid

Toxicity Data: ORL-RAT LD50: 2660 MG/KG

RTECS No.: MA8050000

Glycerin

Toxicity Data: ORL-RAT LD50:12600 MG/KG

RTECS No.: TY2000000

Propylene Glycol

Toxicity Data: ORL-RAT LD50: 20 GM/KG

RTECS No.: AZ5820000

Sodium Alginate

Toxicity Data: ORL-RAT LD50: >5 GM/KG

RTECS No.: YT4860000

Carbamide Peroxide

Toxicity Data: ORL-RAT LD50: NA

RTECS No.: JL6475000

Hydroxyalkyl Phosphonate

Toxicity Data: ORL-RAT LD50: 990 MG/KG

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Section 11: TOXICOLOGICAL INFORMATION (cont.)

RTECS No.: SL1945000

Butylated Hydroxyanisole (BHA)

Toxicity Data: ORL-RAT LD50: 2000 MG/KG

NOTE: Only selected Registry of Toxic Effects of Chemical Substances (RTECS) data is presented here. See actual entry in RTECS for complete information.

Section 12: ECOLOGICAL INFORMATION

No data available on the environmental impact of this product.

Section 13: DISPOSAL CONSIDERATIONS

All disposal methods must be in compliance with all Federal, State/Provincial and local laws and regulations. Regulations may vary in different locations. Waste characterizations and compliance with applicable laws are the responsibility solely of the waste generator.

Section 14: TRANSPORT INFORMATION

	US DOT	IATA	IMO	RID/ADR	Canadian DG
Shipping Name:	Not Regulated	Not Regulated	No Information Available	No Information Available	No Information Available
Hazard Class:	NA	NA			
UN Number:	NA	NA			
Package Group:	NA	NA			

There are no unreasonable risks (health, safety, or property), that this product would pose when transported in commerce. Hazard class definitions (49 CFR, Part 173) are not applicable to this product.

Section 15: REGULATORY INFORMATION

OSHA HAZARD COMMUNICATION STANDARD (29 CFR 1910.1200):

Bausch & Lomb Soothe® Xtra Hydration Lubricant Eye Drops is considered non-hazardous under the Occupational Safety & Health Administration Hazard Communication Standard.

TOXIC SUBSTANCE CONTROL ACT (TSCA):

All ingredients are listed on the TSCA inventory

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Section 15: REGULATORY INFORMATION (cont.)

SARA TITLE III (Superfund Amendments and Reauthorization Act):

SECTION 302 (Extremely Hazardous Substances): No Components Listed

SECTION 311, 312 (Hazard Categories): NA

SECTION 313 (Toxic Chemicals): No Components Listed

CALIFORNIA PROPOSITION 65:

This product contains the following ingredients for which the State of California has found to cause cancer, birth defects or other reproductive harm, which would require warning under the statute: CAS# 25013-16-5, BHA (no significant risk level, 4 mg/day value)

Section 16: OTHER INFORMATION

To the best of our knowledge, the information contained herein is accurate. However, neither Bausch & Lomb Incorporated nor any of its subsidiaries assumes any liability whatsoever for the accuracy or completeness of the information contained herein. Final determination of suitability of any material is the sole responsibility of the user. All materials may present unknown hazards and should be used with caution. Although certain hazards are described herein, we cannot guarantee that these are the only hazards that exist. NO WARRANTY, EXPRESS OR IMPLIED, OF MERCHANTABILITY, FITNESS OR OTHERWISE IS MADE. In no event shall Bausch & Lomb Incorporated or any of its subsidiaries be liable for any special, incidental or consequential damages.